Special Issue On The Drug Trade

Kefauver Reveals: How AMA Revenues Rose After It Dropped Its Seal of Acceptance

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The Low Ethical Content of Our Ethical Drug Industry

The American Medical Association was the first organization to appear here in opposition to S.1552, the Kefauver-Celler bill to do something about the cost and quality of prescription drugs. Its assistant executive vice president, Dr. Ernest B. Howard, as smooth and sedative a witness as the capital has seen in many a day, told the Kefauver committee that he would rely instead on "a free market and a [medical] profession educated . . . a profession fully knowledgeable in a free market." It would take an Ibsen or a Shaw to do justice to this sham. The hearings opened by Senator Kefauver, in the wake of the report his Anti-Trust and Monopoly Subcommittee has just filed (Sen. Rep. No. 448) on administered prices in the drug industry, promise to be a latter day morality play illuminating the realities of our society. In no area of our economy is reliance upon a free market more illusory than in prescription drugs, an area in which a handful of giant drug firms working in close combination exploit the sick, the helpless, the poor and the aged; where pillars of society like the clique which runs the AMA lend their reputations to cover a barrage of misleading advertising to the physician; and where the channels of communication are themselves clogged and poisoned by the power of the drug advertiser.

A Free Market Requires A Free Press

A free market presupposes a free press—a vigilant press. The Kefauver committee's 374-page report on the drug industry is the first study of its kind ever made. It is written on a high level of competence and embodies many stories dug out in a way which would make a reporter's reputation; its exposure of the high costs and high profits of this industry, its shady practices and low moral standards, would make exciting reading in any newspaper. It was brushed off in most newspapers with a few paragraphs. A year and a half ago the Kefauver committee's first revelations in this field did hit the headlines. But now that the formal report is in and hearings have begun on remedial legislation, little attention is paid them. With a few honorable exceptions the editorial pages are silent. But even so conservative a paper as the New York *Herald-Tribune* says (July 7) that the AMA in attacking the Kefauver-Celler bill's regulatory features "and insisting that the medical profession should be the sole watchdog over the efficacy and potential side effects of new drugs" is using "arguments that would have applied almost equally forcibly to the original Pure Food and Drugs Act half a century ago."

The second day of the hearings was marked by a sensation, but in only a few papers did it make even the inside pages. The AMA came to Washington to oppose those sections of the Kefauver-Celler bill which would amend the Federal Food, Drug and Cosmetic Act to give the Food and Drug Administration power to pass on the efficacy as well as the safety of prescription drugs and to establish official or "generic" names for them. These two steps would enable the doctor or the patient to save money as do institutional buyers by ordering under the generic name, with full assurance of quality, without being dependent on higher priced brand names. This would go far to restore competition in many drugs and is opposed by the big drug makers. The AMA came down to argue that the drug industry be allowed instead to police itself. Dr. Hugh H. Hussey, Jr., chairman of the board of trustees of the AMA, outlined a program of this self-regulatory kind on which the AMA proposes to embark. Dr. Hussey gave the game away when Senator Kefauver asked him why he thought it was right for the AMA but not the government to pass on the efficacy of drugs. Dr. Hussey answered, "The important consideration is that we cannot keep a drug off the market."

Up to 1955 the AMA had at least taken steps to keep non-efficacious or falsely advertised drugs out of the pages of its Journal. Until 1955 only advertisers approved by the

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The Wondrous Film-Flam in Wonder Drugs

"While the [drug] industry spokesmen would have us believe that all research is on wonder drugs or better medicinal products this is no more true than the euphemism of postgraduate medical education. They stress that there are many failures for each successful drug. This is true since it is the very essence of research. The problem arises out of the fact that they market so many of their failures. Between these failures which are presented as new drugs and the useless modification of old drugs, the addition of zinc to vitamins is a good example, most of the research results in a treadmill which moves at a rapid pace but goes nowhere. Since so much depends on novelty, drugs change like women's hemlines and rapid obsolescence is simply a sign of motion, not progress, as the apologists would have us believe. . . . I doubt whether there are many other industries in which research is so free of risks. If an automobile does not have a motor, no amount of advertising can make it appear to have one. On the other hand, with a little luck, proper timing and a good promotion program, a bag of asafetida with a unique medical side chain can be made to look like a wonder drug. The illusion may not last long, but it lasts long enough. By the time the doctor learns what the company knew at the beginning, it has two new products to take the place of the old one."

—Dr. A. Dale Console, former medical director of Squibb, at p. 127 of the new Kefauver committee report on Administered Prices: Drugs (Sen. Rep. No. 448).

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AMA's Council on Drugs for its so-called Seal of Acceptance could appear in the pages of the AMA Journal. Dr. Howard explained that the Seal of Acceptance program was abandoned because "it was not as good a program as we should have had." This was true, but it seems that the Seal program was abandoned not because it was not good enough but because it was too strict to suit many large drug advertisers. The Kefauver committee on the second day of the hearings put into the record a series of special reports by the Chicago public relations firm of Ben Gaffin to "determine ways in which the sale of advertising space in JAMA and other AMA publications could be increased." The Gaffin firm declared that "the utilization of the study findings netted the AMA a return of 3600% in increased pharmaceutical advertising for each dollar spent on the research." Gaffin found that the drug industry didn't like the Drug Council because the Council "is always trying to catch it doing something that is crooked." "The survey also found that the Seal of Acceptance helped the small drug advertisers against the big ones. The Gaffin agency boasted that its survey for the AMA brought about "the eventual dropping of the 58-year old Council Seal of Acceptance program." Then the Kefauver committee produced figures to show that the AMA's revenues from advertising by the 22 big drug firms nearly doubled after dropping the Seal of Acceptance. It went from $2,136,864 in 1955 to $4,103,562 in 1960.

After the AMA Dropped Its Seal

The AMA in recent years has become more dependent on drug advertisers. In 1950 its revenue from members and readers was $5,000,000; from advertisers, $2,600,000. Ten years later dues and subscriptions had risen to $5,900,000 but advertising revenue was $7,900,000 and the AMA drew another $1,500,000 or so from the sale of mailing lists and exhibit space for use of the drug manufacturers. Even some of the most famous and reputable of these drug houses have been involved in advertising tactics which hardly qualify them for self-regulation in harness with an organization like the AMA dependent on them for revenue. Here are a few sample cases from those unearthed by the Kefauver report:

Parke, Davis: One of the problems in policing the drug industry is the difficulty of checking on what the "detail men" tell the physicians on whom they call to "sell" new drugs. The drug firm's instructions rarely become a matter of public knowledge. The Kefauver committee, however, did come into possession of the written instructions given detail men by Parke, Davis in the case of the drug Chloramphenicol, sold exclusively in this country under the trade name of Chloromycetin. This has a larger sales volume than any single trade-name ethical drug and is the second largest selling broad spectrum antibiotic.

In June, 1952, the Food and Drug Administration discontinued the certification of this drug after a series of reports that its use was associated in a relatively small number of cases with blood dyscrasias—particularly aplastic anemia, which has a fatality rate of at least 50%. The drug was allowed back on the market after a study by the National Research Council on condition that the drug company be required to warn on the label and in advertisements that it "not be used indiscriminately or for minor infections"

A Bland Answer Turneth Away Senators

Sen. KEFAUVER: I gather about $10 million of your total revenue is from advertising. Apparently about 80% of that comes from the pharmaceutical manufacturers, so that you are getting more revenue out of the pharmaceutical manufacturers than you are from your membership. . . . So can you be objective when the big part, the major part of your revenue comes from the people that you are trying to regulate. . . ?

Dr. [Hugh H.] HUSSEY, Jr. [Chairman of the Board of Trustees of the AMA]: Yes, sir, it is entirely proper that we should be objective and we are objective.

—Senate hearings on S. 1552, July 6

The AMA Does Not Require "The Whole Truth and Nothing But" In Its Ads

Dr. [Irene] TILL [Kefauver Committee Staff Economist]: Mr. Chairman, we would like first to present a couple of ads that were in the Journal of the American Medical Association, one for Aug. 6, 1960, which says: 'Every statement that appears in AMA publications must be backed by substantiated facts or we won't run it. That is why you can rely on what you read about products that are advertised in the pages of the AMA scientific journals. . . .'

Mr. Chairman, we looked at a few ads, and we would first like to point out the ad on DBI, which is an oral anti-diabetic drug, which reads, for Feb. 25, 1961: 'Newest JAMA [Journal AMA] paper reports DBI an 'oral therapy of choice in management of diabetes . . . from the mild stable adult to the severe labile juvenile.' Then it goes on to quote some remarks from that article. Upon examining the article, which is entitled 'Clinical Evaluation', in the JAMA Oct. 1, 1960, we found of the 104 patients studied, all but five had to use insulin along with DBI . . . and we noticed in addition that New and Non-Official Drugs says in its 1961 issue on side effects of this drug DBI: 'The usefulness is limited by the frequency with which gastro-intestinal symptoms such as oxemia, nausea and vomiting occur. . . .' None of these remarks appear any place in the ad. . . .

Sen KEFAUVER: What do you say about that?

Dr. [Hugh H.] HUSSEY, Jr. [Chairman of the Board of Trustees of the AMA]: I have not read the article, Senator. The advertisement does mention some toxic side effects as I heard you read it. The advertisement seemed to. There is one point in connection with advertising that is not strictly relevant to the presentation that has been made, but is relevant to our total consideration of the problem. In my estimation, we must not confuse advertising with education. . . .

* * * *

Sen. KEFAUVER: And you are aware also that Miltown or meprobamate is addictive under certain circumstances? Dr. Hussey, are you aware of that?

Dr. HUSSEY: You used the term addictive, Senator.

Sen. KEFAUVER: Habit-forming.

Dr. HUSSEY: There is some distinction in the sense that dependency is the word applied in the case of this drug.

Sen. KEFAUVER: All right, dependency then. . . .

Dr. HUSSEY: There is that tendency, yes, sir, in some people.

Sen. KEFAUVER: I wish you would look at this advertisement [JAMA March 11, 1961] and see how you justify that with your claims that full information is given. . . ?

Dr. [Ernest B.] HOWARD [Asst Exec V-P of the AMA]: Chairman, may I comment on this item?

Sen KEFAUVER: Yes.

Dr. HOWARD: We do not require in advertising copy that the truth, the whole truth and nothing but the truth, the whole story about a drug, be told in advertising copy.

—Senate Antitrust hearing on S. 1552, July 6.

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because "certain cases of serious blood dyscrasias had been associated" with its use.

A Phoney Spiel for the Detail Men

The Kefauver committee found that Parke, Davis complied fully with these instructions in its advertisements for medical journals, where the editors were familiar with FDA requirements. In those directly mailed to physicians, on the other hand, it watered down the official warning. But in its private instructions for sales talk purposes to its detail men Parke, Davis was downright misleading. Its detail men were instructed to say that Chloromycetin had passed "three intensive investigations," that this represented the "highest compliment" ever tendered its medical staff, and that the drug had been "officially cleared . . . with *no restrictions* on the number or the range of diseases for which Chloromycetin may be administered." The words "no restrictions" were italicized in the instructions to the detail men although the Council had to the contrary recommended that it "not be used indiscriminately or for minor infections" because of the blood disease danger.

Merck: The Kefauver committee first encountered this problem of "side effects" in its very first drug industry hearing, which involved the cortical steroids. The basic discovery in this field was cortisone, used by arthritic sufferers. A variant was Decadron put on the U.S. market by Merck in November, 1958. The need for caution in using Decadron seems to have been well understood within the medical department of Merck & Co. Its director of medical research, Dr. Augustus Gibson, admitted in a letter to the Kefauver committee "that the beneficial effects of cortisone* are unfortunately often accompanied by undesired ones. These may range from simple rounding of the face or easy bruising of the skin to severe mental diseases or spreading of infection." But in ten months Merck captured a fourth of the market in cortical steroids by a vigorous advertising campaign which stressed Decadron's "potency" and minimized its "side effects." Indeed Merck's first "Dear Doctor" letter in November, 1958, informed physicians that the usual adverse side effects for the cortical steroids were absent in Decadron. The Kefauver committee found that Dr. Edward Boland, a noted authority and one of the first to engage in clinical testing of the drug for Merck prior to its release, had concluded that "the overall incidence of adverse reactions" from Decadron was about the same as that of similar derivatives. Yet Merck advertised widely "No worrisome side effects attributable to Decadron have occurred as yet." Dr. Gibson reluctantly conceded to Senator Kefauver, "As of today I would say it is not true."

Pfizer: Dr. Austin Smith, president of the Pharmaceutical Manufacturers Association, pompously assured the Kefauver committee that "the word 'advertising' is perhaps something of a misnomer when it applies to prescription drugs. . . . For the most part, our advertisements are more like scientific treatises which serve the purpose of 'doctor education' in new drugs."

An example of this doctor education cited by the Kefauver committee was the advertising campaign put on by the drug house of Pfizer for Diabenese, a slight molecular modification of a drug known as tolbutamide which the Germans discovered in the early 1950's and which was successfully marketed

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*** Earlier Dr. Gibson explained that he was using the term "cortisone" to cover all of its later derivatives.**

The Morality of Patents on Drugs

"It is also not generally known that most countries of the world do not grant product patents on drugs. 'Process' patents, i.e., patents on methods and processes of producing drugs are granted. But on the product itself 49 out of 77 countries for which information has been obtained do not award patents in the pharmaceutical field. Of the 17 foreign countries for which usable price information was obtained for the [Antitrust and Monopoly] Subcommittee by the State Department, 11 do not grant patents on pharmaceutical products, while only 6 do. Most of these six have either compulsory licensing provisions or price controls on drugs or both. The U.S. is the only major economic power which grants product patents on drugs without imposing any of these limitations or safeguards to the public welfare.

"The practice followed by most other countries of making drugs an exception to their patent laws is based upon the simple moral belief that no one should have the right to withhold from the public products which are vital to the health of mankind. No one, it has been felt, should make a monopoly profit on the sale of such products."

—Kefauver opening hearings on S. 1552, July 5.

Kefauver In Opening Statement Shows The Fabulous Profits of the Drug Industry

"According to the FTC-SEC [Federal Trade Commission] the rate of return on net worth after taxes in the drug industry in 1959 was 18.1% as compared to 10.5% for all manufacturing. According to the First National City Bank of New York, it was 21.9% for 27 leading drug corporations, as compared to 11.6% for all manufacturing. . . .

"I wish to emphasize that these figures are after taxes and after all expenses, including research. The profit rates for a number of individual drug companies are astonishing. Thus Carter Products in 1958 enjoyed a rate of return on its invested capital after taxes of 38.2%; at this rate it would recover its entire investment in less than 3 years. American Home Products made 33.5%; Smith Kline & French 33.1%; Norwich Pharmacal Co. 23.7%; G. D. Searle & Co. 23.2%; Sterling Drug 22.7%; Schering Corp. 21.8%; Parke, Davis 21.6%; U. S. Vitamin and Pharmaceutical Corp. 20.9%; and Warner-Lambert 20.1%. . . .

"Since World War II the stock market quotations on drug companies have soared. Some impression of the extent of the resulting increase in values can be gained by a few examples: In 11 years the stock of American Home Products would have returned $16,480 in dividends for a $10,000 investment. In addition, the capital value of the stock, as reflected in quotations on the New York Stock Exchange, would have risen to $137,200 at the end of 1959. Such a rise represents nearly 14 times the initial investment. Between 1949 and 1959 another company, Smith, Kline & French, paid in dividends more than double the initial cost; its stock appreciated over 24 times, the stock being split 18 for 1 during the 11-year period. The orginal investment of $10,000 at the beginning of 1949 was worth $244,000 at the end of 1959—an appreciation of $243,000—and the investor would in addition have received $20,000 in dividends.

"These and similar profit showings are made by companies which manufacture products that represent the difference between sickness and health and often quite literally the difference between life and death."

—Kefauver opening hearings on S. 1552, July 5.

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The Menace to the Free Market Is Also A Menace to A Free Society

here by Upjohn under the trade name of Orinase. Tolbutamide was an oral drug for diabetes, which hitherto could be treated only by insulin. Pfizer launched Diabenese with an advertising campaign which stressed "almost complete absence of unfavorable side effects," yet the Kefauver committee turned up a memorandum June 8, 1958 from the physician in charge of the testing program for Diabinese before it was marketed in which the President of Pfizer, John E. McKeen, was informed, "In the evaluation of Diabinese we have encountered an incidence of toxicity which, at the least, is not less than that seen with Orinase. We have encountered six cases of jaundice. The jaundice in each instance developed after 3 to 4 weeks of chronic daily treatment with Diabenese." Of 1,992 cases tabulated by this physician, 27 percent reported one or more side effects. This tabulation was dated August 15, 1958. Yet in October Pfizer launched an advertising campaign stressing "almost complete absence of unfavorable side effects," and within a year captured one-sixth of the market for oral anti-diabetic drugs.

What the Kefauver-Celler Bill Would Do

The Kefauver hearings resume July 18. The drug industry has mobilized a battalion of lawyers and press agents to fight improved regulation. The Kefauver-Celler bill attacks the problem from two directions. One is by increasing the power of the Food and Drug Administration to inspect pharmaceutical plants, to keep useless drugs off the market, to license drug firms in order to maintain quality standards, and to establish generic names so as to create a freer market for drugs. The other is by amendment of the anti-trust laws to prevent the drug companies from getting together and deciding in advance which shall have the patent and which the licenses on a new drug, and to require compulsory licensing of product patents for prescription drugs after three years.

The Capitol can be a lonely place for those who take it on themselves to fight the moneyed powers of our society. Senator Kefauver's long and difficult inquiry into so-called administered prices has had to proceed in a heart-breaking semi-obscurity, though it has demonstrated how huge private collectivisms are destroying the free market in steel, in autos, in bread and in drugs. These corporate giants in undercutting the free market also undermine free society. Their power through advertising has reduced a free press to a caricature of its great pretensions. The drug companies also drug the public mind, particularly through the newer media of radio and TV; many of the same companies which produce "ethicals" also sell widely advertised over-the-counter drugs. We devote this entire letter to the drug report and the drug hearings to awaken thoughtful Americans to the need to mobilize support now for the Kefauver-Celler bill. This is one fight which can be won.

Brand vs. Generic Names

"The principal, though not the only reason for this bill [S. 1552] is that ethical drug prices are generally unreasonable and excessive. They are unreasonable whether compared to costs, to profits or to prices in foreign countries With respect to costs, prednisone and prednisolone, leading drugs used by arthritic sufferers, represent a typical case in point. Under the big drug companies' brand names, such as Meticorten or Meticortelone, these products are sold to druggists for around 18 cents a tablet and the suggested price to consumers is 30 cents a tablet. Yet the cost of production for these tablets including tableting, bottling and packaging is no more than 1.5 cents per tablet. An arthritic patient will frequently remain for long periods on a dosage of about 100 of these tablets a month. Thus he pays $30 a month for his medicine, for which his druggist paid around $18 and which cost around $1.50 to produce. . . .

"In the case of unpatented drugs (and this is an important reservation), it is usually possible for the consumer to achieve substantial savings if his physician writes out the prescription in terms of the product's generic or official name rather than in terms of a trade name or some particular company. . . . When sold under the trade name, 'Meticorten', the arthritic drug, prednisone, retails at a list price of approximately 30 cents a tablet. But today when the physician writes out the prescription in terms of the generic name, prednisone can be purchased from drug stores in Washington, D. C., for less than 4 cents a tablet."

—Kefauver opening hearings on S. 1552, July 5.

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